Bridge2AI eConsent - Addendum (MIT) - English

Please complete the form below.

Thank you!

Site Specific Information and Authorization to Collect, Use, and Share your Health Information

Title: Bridge2AI Voice Data Acquisition

Site # ___ 000023_____

Site Name: Weill Cornell Medicine

Local PI/ Phone number: Anais Rameau, (917) 543-9172

Overview: The information contained in this document is additional information specific to the research site where you are enrolling. None of the information within this document supersedes the information in the attached overall consent. This document provides you with additional information about the local site where you're enrolling in the research. If you have any concerns regarding information within this document please contact the local Principle Investigator, whose contact information is included above.

Compensation

You ***will not*** receive compensation for participating in this study.

Policy/Procedures for Research Related Injury

The Policy and Procedure for the Sponsor are as follows:

The Sponsor, University of South Florida, will not pay for care necessitated by a research related injury.

The Policy and Procedure for Weill Cornell Medicine are as follows:

We are obligated to inform you about Weill Cornell Medicine's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from Weill Cornell Medicine. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

Whom do I Call if I Have Concerns, Questions, or Complaints?

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Anais Rameau at (917) 543-9172, anr2783@med.cornell.edu.

If you would like to speak to someone other than the researchers concerning complaints or questions about your rights as a research participant, or you would like to offer input, please contact the WCM Institutional Review Board. Direct your questions to the Institutional Review Board at:

Institutional Review Board	(646) 962-8200
1300 York Avenue, Box 89	irb@med.cornell.edu
New York, New York 10065	

You may also submit concerns about your rights as a research participant without giving your name ("anonymously") by using (866) 293-3077 or http://www.hotline.cornell.edu/.

Authorization to Use and Disclose Protected Health Information (HIPAA Language)

Purposes for Using or Sharing Protected Health Information: If you decide to join this study, Weill Cornell Medicine researchers need your permission to use your protected health information according to a regulation called the HIPAA (Health Insurance Portability & Accountability Act) Privacy Rule. If you give permission, Weill Cornell Medicine researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

Voluntary Choice: The choice to give Weill Cornell Medicine researcher's permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for Weill Cornell Medicine researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from Weill Cornell Medicine.

Protected Health Information to Be Used or Shared: Government rules require that researchers get your permission (authorization) to use or share your protected health information. Your medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your medical records and from any test results, which includes your research record, all of your past, current or future medical and other health records held by WCM, other health care providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to records related to HIV/AIDs, mental health, substance abuse, and/or genetic information.

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the study sponsor, the WCM Institutional Review Board, inspectors who check the research, government agencies and research study staff. The researchers could also share your protected health information with the following groups of people:

- The medical staff that takes care of you as a participant of this study and those who are part of this research study;
- Each research site for this study including: University of South Florida (USF), Weil Cornell

Medicine (WCM), Massachusetts Institute of Technology (MIT), University of Toronto (UofT), Vanderbilt University Medical Center (VUMC), Mount Sinai Hospital (MSH), Hospitals for Sick Children (HSC), Boston Children (BC), Massachusetts Eye and Ear (MEEI), Emory University, and Cleveland Clinic

- Any laboratories, pharmacies, or others who are part of the approved plan for this study;
- The USF Institutional Review Board (IRB) their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research;
- All designated review committees such as the IRB at each collaborating institution
- Data Safety Monitoring Boards or others who monitor the data and safety of the study

The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule. We will use and share your information only as described in this form; however, people outside WCM who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

FUTURE RESEARCH AND RESEARCH REPOSITORY

What is a Research Repository? A research repository (database) is a collection of information from many individuals. This includes information from individuals directly, from health and medical records, and can sometimes include specimens (like your tissue). The repository (database) may use and/or share the information with researchers for future use, which means they can use the information for purposes beyond the purpose of the current project.

In order to store the information/samples collected in this study for possible future use in someone else's research, you are being asked to make some decisions about your data/sample(s) included in this study. Sometimes people do not want their data/samples stored for future use. We are seeking your additional permission because without that your permission would otherwise only cover use in this study.

The repository (database) will include voice recording and associated data stripped of all identifiable information (such as name, email, address etc.) about each person whose information is collected. However, the repository does not share information with researchers unless the researchers agree to keep the information confidential. Your data/samples will not be sold for profit and any research which uses your data/sample(s) will have to be approved.

Choose to include one of the two paragraphs below when applicable to your study:

In order to participate in this study, you must also agree to allow your data (including voice, speech and respiratory sound data, demographic data, previously completed imaging data, and surveys and/or validated questionnaires related to your diagnosis) to be used for future research within Weill Cornell Medicine, and/or at outside institutions and private companies, in a research repository. If information goes to an outside entity, then Weill Cornell Medicine cannot ensure the Privacy Rule is followed. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- The medical staff that takes care of you as a participant of this study and those who are part of this research study;
- Each research site for this study including: University of South Florida (USF), Weil Cornell Medicine (WCM), Massachusetts Institute of Technology (MIT), University of Toronto (UofT), Vanderbilt University Medical Center (VUMC), Mount Sinai Hospital (MSH), Hospitals for Sick Children (HSC), Boston Children (BC), Massachusetts Eye and Ear (MEEI), Emory University, and Cleveland Clinic
- Any laboratories, pharmacies, or others who are part of the approved plan for this study;
- The USF Institutional Review Board (IRB) their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research;
- All designated review committees such as the IRB at each collaborating institution
- Data Safety Monitoring Boards or others who monitor the data and safety of the study

RESEARCH PARTICIPANT: On the checklist below, please indicate if you would permit the researchers to store and/or share your voice, speech, and respiratory sound data, demographic data, previously completed imaging data, and survey and/or validated questionnaire answers for future research.

We will use and share your information only as described in this form; however, people outside WCM who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

By checking "Yes" and signing this consent form, you agree to give your data and Protected Health Information to Weill Cornell Medicine for research purposes.

☐ **YES,** I give permission for my voice, speech, and respiratory sound data, demographic data, previously completed imaging data, and survey and/or validated questionnaire answers to be stored for future unspecified research by the researchers of this study. I understand that the data and/or samples will be stored for at least 50 years and will be destroyed after the research is completed.

☐ **YES**, I give permission for my voice, speech, and respiratory sound data, demographic data, previously completed imaging data, and survey and/or validated questionnaire answers to be **shared** with other qualified **researchers** for future research.

By signing this consent form, you agree to give these voice, speech, and respiratory sound data, demographic data, previously completed imaging data, and survey and/or validated questionnaire answers to Weill Cornell Medicine for future research.

If you withdraw consent at a future time, we will be unable to destroy your collected voice, speech, and respiratory sound data, demographic data, previously completed imaging data, and survey and/or validated questionnaire answers, as there will be no way to link the data to you.

RESEARCH PARTICIPANT: On the checklist below, please indicate if you would permit the researchers to store and/or share your voice, speech, and respiratory sound data, demographic data, previously completed imaging data, and survey and/or validated questionnaire answers for future research.
We will use and share your information only as described in this form; however, people outside WCM who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential - but we cannot guarantee that your information will not be re-disclosed.
By checking "Yes" and signing this consent form, you agree to give your data and Protected Health Information to Weill Cornell Medicine for research purposes.

YES, I give permission for my voice, speech, and respiratory sound data, demographic data, previously completed imaging data, and survey and/or validated questionnaire answers to be stored for future unspecified research by the researchers of this study. I understand that the data and/or samples will be stored for at least 50 years and will be destroyed after the research is completed.	◯ Yes ◯ No
YES, I give permission for my voice, speech, and respiratory sound data, demographic data, previously completed imaging data, and survey and/or validated questionnaire answers to be shared with other qualified researchers for future research.	◯ Yes ◯ No

By signing this consent form, you agree to give these voice, speech, and respiratory sound data, demographic data, previously completed imaging data, and survey and/or validated questionnaire answers to Weill Cornell Medicine for future research.
If you withdraw consent at a future time, we will be unable to destroy your collected voice, speech, and respiratory sound data, demographic data, previously completed imaging data, and survey and/or validated questionnaire answers, as there will be no way to link the data to you.

Consent to Take Part in Research and Authorization for the Collection, Use and Disclosure of Health Information

I freely give my consent to take part in this study and authorize that my health information as agreed above, be collected/disclosed in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me. I understand that by filling out the best future contact below, I am consenting to be contacted in the future for further voice data collection if long term follow up is required as part of an eventual extension of this grant after the 4-year duration.

Please select one of the three statements below that you consent to.

_ I consent to having all data I submit shared only with the researchers of this study.

_ I consent to having all data I submit shared with the researchers of this study and to having my audio recordings and de-identified written responses shared with other qualified researchers.

_ I consent to having all data I submit shared with the researchers of this study and to having my audio recordings and de-identified written responses shared with other qualified researchers as well as publicly in the form of an open-source database.

_____ _____

Signature of Person Taking Part in Study [Authorization] Date

_____

Printed Name of Person Taking Part in Study

_____

Best form of contact for future voice data collection
(leave blank if you do not want to be contacted)

Signature of Person Taking Part in Study
[Authorization]

_____

Printed Name of Person Taking Part in Study

_____

_____